K111212

JUL 28 2011

p. 1/2

Summary of Safety and Effectiveness

Date: April 12, 2011

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
Cheryl Hastings
Principal Consultant
Phone: 574-527-4220

Product	Product Code	Regulation and Classification Name
SMR Revision Stems	HSD	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis per 21 CFR 888.3690
	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description:

The SMR Revision Stems are made from Ti6Al4V (ISO 5832-3 / ASTM F1472). They are available in two versions: cemented and uncemented.

SMR Revision cemented stems are characterized by a cylindrical shape in the distal region while the proximal part is tapered and fluted. The whole surface of the stem is polished.

SMR Revision uncemented stems are characterized by a cylindrical shape in the distal region while the proximal part is tapered and finned. The whole surface of the stem is sand-blasted.

Both the stems are provided with a male taper for the coupling with the humeral bodies and a safety screw is used to help initially seat the body on the stem taper. SMR Revision Stems can be used for anatomical (when coupled with trauma and election humeral bodies, cleared via K100858 and K101263) shoulder replacements.

SMR Revision cemented stems are intended to be used with bone cement; SMR Revision uncemented stems are intended for press-fit applications.

Intended Use: The SMR Revision Stems are indicated for the treatment of fractures or revision of a failed primary component in total or hemi-shoulder replacement. Total or hemi-shoulder replacement is indicated for patients suffering from disability due to:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;

- Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods
- Cuff tear arthropaty;
- Revision of a failed primary component.

Predicate Devices:

- SMR Shoulder System (Lima-Lto, K100858) and SMR Uncemented Shoulder System (Lima-Lto, K101263);
- Global FX humeral stem (DePuy, K984541);
- Aequalis Reversed Shoulder Prosthesis (Tornier, K030941);

Comparable Features to Predicate Device(s):

The SMR Revision stems are similar to the predicate devices in terms of intended use, indications, design and materials. The SMR Revision stems and the predicates are all intended for partial or total primary shoulder joint replacement. The SMR Revision stems are intended for cemented or uncemented use, depending on the design, as are the predicate humeral stems.

The SMR Revision stems are provided with the same taper connection to join the SMR system humeral stems and the humeral bodies components cleared via K100858 and K101263. The surface finishing and geometrical features are the same as the SMR systems primary stems. Revision stems length and diameters are similar to those of DePuy Global FX and Tornier Aequalis shoulder systems.

The SMR Revision stems are manufactured from the same or similar materials as the predicate devices. The SMR humeral stems are manufactured from Ti6Al4V while the Global FX and Aequalis stems are manufactured from cast CoCrMo.

Non-Clinical Testing:

The SMR systems has undergone fatigue testing to demonstrate both the strength of the humeral stem and the post-fatigue strength of the modular connections. All mechanical testing was done on worst case components or constructs. Where possible, standard test methods were used to allow comparison to testing of the predicate devices. The testing results demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the SMR Shoulder System to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Limacorporate S.p.A
% Ms. Cheryl Hastings
Principal Consultant
P.O. Box 696
Winona Lake, Indiana 46590-696

JUL 28 2011

Re: K111212
Trade/Device Name: SMR Revision Stems
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: April 12, 2011
Received: April 29, 2011

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111212 p. 1/1

510(k) Number (if known): Unknown

Device Name: SMR Revision Stems

Indications for Use:

SMR Revision Stems
Indications for Use

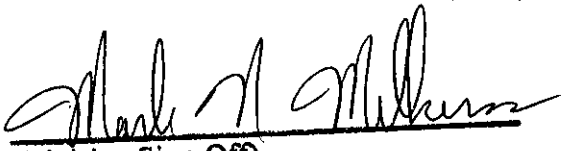
The SMR Revision Stems are indicated for the treatment of fractures or revision of a failed primary component in total or hemi-shoulder replacement.
The components are intended for use in cemented and uncemented applications according to their labeled indication.
Total or hemi-shoulder replacement is indicated for patients suffering from disability due to:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods
- Cuff tear arthropathy;
- Revision of a failed primary component.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111212